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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,031	09/21/2001	David Margolis	A8163	6530

7590 08/06/2002  
SUGHRUE, MION, ZINN  
MACPEAK & SEAS, PLLC  
2100 Pennsylvania Avenue, NW  
Washington, DC 20037-3213

EXAMINER
PAPPU, SITA S

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/957,031

Applicant(s)

MARGOLIS ET AL.

Examiner

Sita Pappu

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 89-190 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 89-190 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

IDS and preliminary amendment filed 09/21/2001 (papers 2 and 3) have been entered. Claims 89-190 are pending in the instant application.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 89-94, 95-99, 100, 109-110, 111-116, 117-122, 123-127, 128, 137-140, 141-148, 149-154, 155-159, 160, 169-171, 172-178, 179-190, drawn to a composition comprising a vector delivery structure, wherein the binding protein is Rep 68 or Rep78, and methods of in vitro transformation and ex vivo treatment of a subject, classified in class 514, subclass 2+.
- II. Claims 89-94, 100-101, 109-110, 117-122, 128-129, 137-140, 149-154, 160-161, 179, 181-182, 184-185, 187-190, drawn to a composition comprising a vector delivery structure, wherein the binding protein is an integrase that is not Rep 68 or Rep78, and methods of in vitro transformation and ex vivo treatment of a subject, classified in class 514, subclass 2+.
- III. Claims 89-94, 102, 109-110, 117-122, 130, 137-140, 149-154, 162, 179, 181-182, 184-185, 187-190, drawn to a composition comprising a vector delivery structure, wherein the binding protein is helicase, and methods of in vitro transformation and ex vivo treatment of a subject,, classified in class 514, subclass 2+.

- IV. Claims 89-94, 103, 109-110, 117-122, 131, 137-140, 149-154, 163, 179, 181-182, 184-185, 187-190, drawn to a composition comprising a vector delivery structure, wherein the binding protein is a DNA excision enzyme, and methods of in vitro transformation and ex vivo treatment of a subject,, classified in class 514, subclass 2+.
- V. Claims 89-94, 104, 109-110, 117-122, 132, 137-140, 149-154, 164, 179, 181-182, 184-185, 187-190, drawn to a composition comprising a vector delivery structure, wherein the binding protein is an isomerase, and methods of in vitro transformation and ex vivo treatment of a subject,, classified in class 514, subclass 2+.
- VI. Claims 89-94, 105, 109-110, 117-122, 133, 137-140, 149-154, 165, 179, 181-182, 184-185, 187-190, drawn to a composition comprising a vector delivery structure, wherein the binding protein is a telomerase, and methods of in vitro transformation and ex vivo treatment of a subject, classified in class 514, subclass 2+.
- VII. Claims 89-94, 106, 109-110, 117-122, 134, 137-140, 149-154, 166, 179, 181-182, 184-185, 187-190, drawn to a composition comprising a vector delivery structure, wherein the binding protein is a DNA repair enzyme, and methods of in vitro transformation and ex vivo treatment of a subject, classified in class 514, subclass 2+.
- VIII. Claims 89-94, 107, 109-110, 117-122, 135, 137-140, 149-154, 167, 179, 181-182, 184-185, 187-190, drawn to a composition comprising a vector

delivery structure, wherein the binding protein is a protein that has gene regulatory activity, and methods of in vitro transformation and ex vivo treatment of a subject,, classified in class 514, subclass 2+.

- IX. Claims 89-94, 108, 109-110, 117-122, 136, 137-140, 149-154, 168, 179, 181-182, 184-185, 187-190, drawn to a composition comprising a vector delivery structure, wherein the binding protein is a protein that facilitates transport to or uptake by the nucleus of the host cell, and methods of in vitro transformation and ex vivo treatment of a subject, classified in class 514, subclass 2+.

Claims 89-94, 109-110, 117-122, 137-140, 149-154, 179, 181-182, 184-185, 187-190 embrace the inventions of Groups I-IX. Should one of these Groups be elected, claims 89-94, 109-110, 117-122, 137-140, 149-154, 179, 181-182, 184-185, 187-190 will be examined only to the extent they encompass the elected subject matter.

Claims 100, 128, 160 embrace the inventions of Groups I and II. Should one of these Groups be elected, claims 100, 128, 160 will be examined only to the extent they encompass the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IX are directed to compositions and methods that comprise different proteins that are structurally different and they have different modes of operation, different functions, or different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

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matter, restriction for examination purposes as indicated is proper. Further, the search required for one Group is not required for other Groups, restriction for examination purposes as indicated is proper.

### ***Election***

Claims 179-190 are generic to a plurality of disclosed patentably distinct species comprising nucleotide sequences that express a molecule that can treat various disorders and comprise: a normal beta globin gene, a normal gene for adenosine deaminase, a normal p47 phox gene, a normal p67 phox gene, a gene encoding antisense RNA against a transforming oncogene contributing to leukemia or lymphoma (claims 179-181, 188), a normal gene for C1 complement protein inhibitor, a normal gene for a clotting factor, and a normal gene for insulin (claims 182-184, 189), p53, rb (retinoblastoma gene product), ras, myc, fas ligand, and surface receptors (claims 185-187, 190). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308 4242 for regular communications and (703) 872 9307 for After Final communications.

Art Unit: 1636

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

S. Pappu  
July 30, 2002

*Anne-Marie Baker*  
ANNE-MARIE BAKER  
PATENT EXAMINER

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